K112907

510(k) Summary

DEC 22 2011

Date Summary Prepared: 30 September 2011

510(k) Sponsor:
Medos International SARL
Chemin-Blanc 38
Le Locle
CH 2400
Switzerland

Establishment Registration number: 3008114965

Contact Person:
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Raynham
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USA

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Device Manufacturer:
Medos International SARL
Chemin-Blanc 38
Le Locle
CH 2400
Switzerland

Trade Name of Device: CONFIDENCE High Viscosity Spinal Cement

Part Numbers:
183907001 (16 g Unit Size)
183901001 (20 g Unit Size)

Common Name: PMMA Bone Cement

Classification Name:
Cement, bone, vertebroplasty
Product Code: NDN

Equivalent to:
Disc-O-Tech Confidence High Viscosity Spinal Cement (K060300)
DePuy Spine Vertebroplastic™ Radiopaque Bone Cement (K071927)

Device Description:

CONFIDENCE High Viscosity Spinal Cement is self-curing, radiopaque, polymethyl methacrylate (PMMA) cement, for filling of spinal vertebral body defects, in order to provide stabilisation of the vertebral body and pain relief.

Indications for Use:

CONFIDENCE High Viscosity Spinal Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (haemangioma), or malignant lesions (metastatic cancers, myeloma).

Contra-indications for Use:

The use of CONFIDENCE High Viscosity Spinal Cement is contraindicated in patients presenting with any of the following conditions:

- Non-pathological, acute, traumatic fractures of the vertebra.
- Patient clearly improving on medical therapy.
- Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture
- Spinal stenosis (> 20% by retropulsed fragments).
- Compromise of the vertebral body or walls of the pedicles.
- Compromise or instability of vertebral fractures due to posterior involvement.
- Haemorrhagic diathesis.
- Anatomical damage of the vertebra that prevents a safe access of the needle to the vertebral body.
- Vertebral body collapse to less than 1/3 (33%) original height.
- Vertebral plana (collapse >90%).
- Active or incompletely treated infection.
- Coagulopathy or inability to reverse anti-coagulant therapy (both during and approximately 24 hours post-procedure).
- Severe pulmonary insufficiency.
- Sensitivity to any of the components of the CONFIDENCE High Viscosity Spinal Cement.

Basis for Substantial Equivalence:

The Medos International SARL CONFIDENCE High Viscosity Spinal Cement has identical intended use and indications for use to the predicate devices Disc-O-Tech Confidence High Viscosity Spinal Cement (K060300) and DePuy Spine Inc Vertebroplastic™ Radiopaque Bone Cement (K071927).

The packaging of the subject device is equivalent to the predicate device Disc-O-Tech Confidence High Viscosity Spinal Cement (K060300), and the manufacturing and sterilization methods are the same as both predicate devices. Chemical composition of the Medos International SARL CONFIDENCE High Viscosity Spinal Cement is similar to

subject devices, and testing has confirmed the devices to have comparable performance characteristics.

Based on the similarities in indications, intended use, design, materials, method of manufacture and the results of performance testing, Medos International SARL believes that the subject device CONFIDENCE High Viscosity Spinal Cement is substantially equivalent to the previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 22 2011

Medos International SARL
% DePuy Spine, Inc.
Ms. Robin DiNardo
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K112907
Trade/Device Name: CONFIDENCE High Viscosity Spinal Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: September 30, 2011
Received: October 03, 2011

Dear Ms. DiNardo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: CONFIDENCE High Viscosity Spinal Cement

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Prescription Use ___YES___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___NO___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112907